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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JESSICA R. DESNOYER and STEPHEN D. PACETTI

Appeal 2009-009565
Application 10/750,312
Technology Center 1700

Before PETER F. KRATZ, JEFFREY T. SMITH, and
MICHAEL P. COLAIANNI, *Administrative Patent Judges*.

KRATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1, 4-9, 11, 13, 14, and 19-25. We have jurisdiction pursuant to 35 U.S.C. § 6.

Appellants' claimed invention is directed to a stent and a stent mandrel supporting the stent. As reported by Appellants, a common treatment for blood vessel occlusions involves the use/insertion of one or more stents, which act as scaffoldings to physically hold open the affected vessels (Spec. 1). Appellants illustrate a conventional stent 10 that includes a plurality of radially expandable struts 12 in drawing Figure 1.

Appellants explain that a stent can be additionally used as a vehicle for providing biological therapy via the application of a coating that includes a medication to the stent (Spec. 1 and 2). For therapeutic purposes, drugs need only be released from the abluminal stent surfaces, and possibly stent sidewalls, according to Appellants. However, Appellants observe that the application of a medicament to a stent, usually with a polymer and solvent, via prior art spray application or dipping techniques, also provides the luminal surfaces of the stent with unnecessary coating (Spec. 2). Aside from the obvious waste, this result is said to be detrimental to the delivery of the stent to the desired interior vessel location and the mechanical integrity of the coating (Spec. 2-3).

Appellants' mandrel for holding the stent and the stent reportedly allows for the application of a therapeutic coating to the stent in a manner that avoids or significantly reduces the deposit of the coating in a detrimental amount and way to a stent luminal surface (Spec. 3 and 4, App. Br. 2-5).

Claims 1, 9, and 23 are illustrative and reproduced below:

1. A stent and a stent mandrel support supporting the stent, the stent comprising a plurality of struts, the support comprising:

a first member to contact a first end of the stent;

a second member to contact a second end of the stent;

and

a third member connecting the first member to the second member and extending through a longitudinal bore of the stent, the third member shaped and/or sized to eliminate or substantially prevent a coating from being formed on a luminal surface of the stent during application of a coating substance to the stent.

9. A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a member to penetrate at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent, the member including outward projecting walls, the length of at least one of the walls being not less than 25% of the length of the stent.

23. A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a member penetrating at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent, the member including outwardly projecting walls disposed around the circumference of the mandrel, wherein each of the walls converge with its neighboring wall at an angle.

In addition to the relied on admitted prior art teachings advanced by the Examiner, the Examiner further relies on the following prior art references as evidence in rejecting the appealed claims:

Rosenbluth	4,762,128	Aug. 9, 1988
Hattler	4,846,791	Jul. 11, 1989

Tower	5,389,106	Feb. 14, 1995
Berg	5,674,208	Oct. 7, 1997

The Examiner maintains the following grounds of rejection:

Claims 1 and 4-8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hattler in view of Berg. Claims 1 and 4-8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hattler in view of Tower. Claims 9, 11, 13, 14, and 19-25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hattler in view of Rosenbluth and alleged admitted prior art.

We reverse the above-identified rejections.¹ Our reasoning follows.

All of the appealed claims are drawn to a stent and a mandrel for supporting the stent.

Hattler is directed to a multi-lumen catheter. Hattler forms a plurality of lumens by inserting a divider 30 into an expandable tube catheter 10 (Figs. 1, 7 and 8). This is done after a hollow needle 20, through or over which the catheter was introduced into a blood vessel, is withdrawn from the blood vessel (col. 4, l. 4- col. 5, l.15; col. 6, l. 27-52; Figs. 4-6). The expandable tube catheter of Hattler is made of expandable material, such as latex, vinyl, or silicon rubber and the divider is made from a material having anti-friction properties, such as Teflon or nylon (col. 4, ll. 20-22; col. 5, ll. 16-24).

Berg is drawn to an intravascular flexible catheter that includes a metallic braided wire support member located between inner and outer tubular members.

¹ No other grounds of rejection are before us for review.

Tower is directed to an expandable intravascular stent comprising a distensible frame useful for supporting the wall of a blood vessel. Tower discloses that a stent 10 can be carried on a mandrel 12 during manufacture of the stent and that a synthetic polymer membrane 28 can be bonded to the formed wire sleeve 11 by a dipping process resulting in the polymer membrane spanning the interstices of the formed stent (col. 3, l. 23 - col. 4, l. 35). The stent is removed from the mandrel after formation. An inflatable balloon catheter 30 is disclosed by Tower for placing the formed stent in a blood vessel (col. 4, ll. 36-68; Figs. 2 and 3).

Rosenbluth is directed to an apparatus for treating hypertrophy of the prostate gland. The apparatus includes an expansible catheter that can carry an expansible tubular stent for transurethral insertion and placement of the stent within a stenotic region of a urethral lumen caused by a hypertrophied prostate gland (abstract).

ISSUES

Has the Examiner furnished a plausible rationale/reason to modify any identified features of the multi-lumen catheter of Hattler with any identified features of Berg, Tower, or Rosenbluth and the admitted prior art in a manner so as to result in a stent and mandrel support for the stent as called for in any of the rejected claims?

We answer in the negative for reasons argued by Appellants in the Appeal Brief and the Reply Brief.

Concerning each of the first two obviousness rejections over claims 1 and 4-8, the Examiner correctly acknowledges that Hattler does not explicitly disclose a stent comprising a plurality of struts, as required by

claim 1. In considering Hattler, the Examiner seems to have overlooked or misapprehended the relevance of Hattler to the claimed subject matter because the Examiner has not presented a reasonable explanation as to how Hattler discloses or suggests a stent, even without struts, and/or a mandrel for support of a stent, as recited in claim 1, by referencing the catheter depicted in Figures 1-3 of Hattler (Ans. 3-7). This is made apparent by a reading of Hattler and Appellants' reasonable descriptions of Hattler and the claimed stent and mandrel, as set forth in the Appeal Brief (App. Br. 2, 3, 6-8, 13-16).

Regarding the first obviousness rejection, the Examiner turns to Berg for an alleged disclosure of a stent comprising a plurality of struts. However, the Examiner has not proffered a rational basis for modifying the multi-lumen catheter of Hattler in manner to result in a stent and mandrel combination as recited in claim 1.

In this regard, Hattler is concerned with the formation of a multi-lumen catheter tube by using a divider with larger outside dimensions than the tube. The divider is inserted into the flexible tube after the tube has been inserted into a blood vessel (Hattler, Figs. 1 and 4-8). As explained by Appellants (App. Br. 13), the flexible catheter tube 10 radially expands inside a blood vessel as the divider 30 is put in place to form multiple lumens inside the tube. Hattler is not directed to a stent or a mandrel for supporting a stent, as one of ordinary skill in the art would understand. Berg is likewise directed to a catheter, not a stent or a stent support mandrel. Thus, the Examiner's conclusory comments do not explain why one of ordinary skill in the art would have been led to somehow modify the flexible tube 10 of Hattler by employing the wire braid of Berg to stiffen the tube of

Hattler in manner so as to result in the formation of a stent with struts, and a mandrel support as claimed from a modification of the multi-lumen tube of Hattler (Reply Br. 1).

Turning to the second obviousness rejection of claims 1 and 4-8 over Hattler and Tower, the Examiner has similarly failed to present a reasoned basis for a particular modification of Hattler's catheter that would result in a stent supported on a mandrel, as required by claim 1, based on any particularly identified teachings of Tower. In this regard, we are cognizant that Tower discloses an intravascular stent and mandrel combination (Fig. 1).

Tower's mandrel structure is used, at least in part, for forming a stent and providing the stent with a synthetic polymer membrane 28 that can be bonded to a stent wire sleeve 11 by a dipping process. This apparatus allows for the polymer membrane to span the interstices of the formed stent (Fig. 1; col. 3, l. 23 - col. 4, l. 35). However, the Examiner does not predicate the stated rejection on a proposed modification of the Figure 1 stent and mandrel combination of Tower. Rather, and like in the first stated rejection, the Examiner proffers an obviousness rejection based on a modification of the catheter of Hattler. In this instance, the proposed modification is apparently based on the dissimilar balloon catheter stent delivery system and stent of Tower (Ans. 6; Tower, Figs. 2-7). Here, again, the Examiner has not proffered a rational basis for converting, in some way, the multi-lumen catheter of Hattler into a stent and mandrel support based on the balloon delivery system for a stent taught by Tower.

The Examiner's obviousness rejection of claims 9, 11, 13-14, and 19-25 over Hattler in view of Rosenbluth and admitted prior art is similarly

flawed as it is based on the Examiner's misreading of the catheter divider 30 of Figures 12 and 13 of Hattler as a mandrel together with the catheter tube 10 as somehow correlating with a mandrel assembly. In this regard, the Examiner has not presented a reasoned basis for modifying the multi-lumen catheter structure of Hattler to form a stent and mandrel support as claimed based on the expansible inflation catheter carrying an expansible tubular stent for transurethral insertion and placement of the stent within a stenotic region of a urethral lumen as taught by Rosenbluth and based on the admittedly old stent having a plurality of struts of Appellants' Figure 1.

Rosenbluth coats a stent and balloon catheter with a lubricant prior to positioning the stent within the prostatic urethra as pointed out by the Examiner (Ans. 8). However, this disclosure does not furnish any reasonable impetus for one of ordinary skill in the art to convert the dissimilar multi-lumen catheter of Hattler into a stent and a mandrel support combination as Appellants' claim, as basically argued by Appellants (App. Br. 9-12; Reply Br. 2-4).

CONCLUSION

On this record, the Examiner has not furnished a reasoned basis for the proposed modifications of Hattler based on the several secondary references applied in the maintained obviousness rejections.

ORDER

The Examiner's decision to reject the appealed claims is reversed.

REVERSED

Appeal 2009-009565
Application 10/750,312

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